REMARKS

Reconsideration and further examination are requested.

1. Disposition of Claims

Claims 1, 9-10, 13, 15, 19, 22-24, 29, 33, 40-43, 45, 47-48, 51-52, 56, 60, 62, 73-74, 82-83, 86, 88, 92, & 94-97 are pending in this application.

Claim 1 is currently amended. Support for this amendment is found, e.g., in claim 17 as-filed. Claim 19 is currently amended to comport to antecedent. See Substance of the interview below.

Claims 17 & 90 are canceled without prejudice or disclaimer.

Claims 33, 40-43, 45, 47-48, 51-52, 56, 60-62, 73-74, 82-83, 86, 90, 92, & 94-97 have been withdrawn from consideration. The amendments to claims 33, 40, 73-74, & 92 should facilitate rejoinder. Support for each amendment of claim 33 & 40 is found, e.g., in claim 17 as-filed. Claims 73-74 are currently amended to correct an inadvertent typographical error. Claims 92 & 94 are currently amended to comport to antecedent.

Claims 1, 9-10, 13, 15, 19, 22-24, and 29 are rejected.

2. Substance of the interview

The Examiner is thanked for granting and conducting the interview. The Examiner's suggestion to insert claim 17's language into claim 1 is appreciated and adopted. Further Substance of the interview can be learned by reading following points in the next sections.

3. Rejections under 35 U.S.C. § 112¶2

Claims 1, 9-10, 13, 15, 19, 22-24, and 29 were rejected under 35 U.S.C. § 103(a) as being indefinite for not defining the term percentage. Outstanding Office action ("OOa") ¶ 6. Preliminarily, regarding canceled claim 17, the rejection should be withdrawn. Regarding the other rejected claims, the present version of the claims avoids this issue as they are amended as suggested by the Examiner. Specifically, claims 1 & 29 each recite *weight ratio.* Thus, the rejection should be withdrawn.

4. Rejections under 35 U.S.C. § 103(a)

Claims 1, 9-10, 13, 15, 17, 19, 22-24, and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lapidot et al. (US Pub. No. 2002/0064541). OOa ¶ 8. Preliminarily, regarding canceled claim 17, the rejection should be withdrawn. Regarding the other rejected claims, the record is sufficiently developed and will not be repeated here. The present rejection is traversed, because obviousness is determined in view of the *Graham* factors, several of which are in dispute here.

More specifically, claim 1 recites a pH in the following language:

> *wherein the microcapsular shell comprises at least one inorganic polymer comprising polymerized precursors obtained by in-situ polymerization of said precursors in a pH in the range of 2 to 7;*

a weight ratio in the following language:

> *wherein the weight ratio of said precursors to said core material is in the range of 5/95 to 25/75 ...;*

and a core material concentration in the following language:

> *wherein the concentration of the core material based on total weight of the microcapsules is 96% to 99% w/w.*

Each is addressed under a separate header.

The pH

According to the Examiner, Lapidot teaches a "pH of 7.4 (Example 8)" that is "approximate[ly] the presently claimed range." OOa, p. 4. In other words, the Examiner found that Lapidot teaches a pH of 7.4 (in Example 8), which is approximately within the presently recited pH, e.g., pH 7.0, which therefore makes using the recited obvious over Lapidot.

What is misapprehended or overlooked is the fact that Lapidot's Example 8 does not teach one of ordinary skill in the art how to make Lapidot's microcapsules. Instead, it teaches how to induce Lapidot's microcapsules into releasing their content. Lapidot, ¶¶ 264-71; see also, Exs. 9-10 (showing release due to rubbing or drying). Example 8's pH = 7.4 was chosen, in part, "to simulate physiological conditions of the epidermis." Lapidot, ¶¶ 264-65 (¶264 for quote, ¶265 for pH). Simulated physiological conditions of the epidermis do not seem relevant to a method of making via *in-situ polymerization* as recited in claim 1.

Other examples of Lapidot, however, do teach alkaline pH 10, Lapidot Exs. 4-6, or 11.5. Lapidot, Exs. 1-3. Clearly Lapidot's strongly alkaline pH 10-11.5 is different than *a pH in the range of 2 to 7* as recited in claim 1. As such, Lapidot teaches a different pH than that found by the Examiner. For this reason, the rejection should be withdrawn.

Weight ratio

As noted above, claim 1 recites a *weight ratio* in the following language: *wherein the weight ratio of said precursors to said core material is in the range of 5/95 to 25/75 ....* Each of the *core material* and *precursors* is defined in the as-filed specification at page 3, ll. 11-19. For example, the *"core material* "refers to the inside part of the microcapsules comprising the active ingredient [see page 3, ll. 24-27] that is surrounded by the shell of the microcapsule. This term refers to any material present in the core, both the active ingredient and the excipients such as the liquid carrier." Specification at page 3, ll. 11-14

Regarding this *weight ratio*, the Examiner cited Lapidot's paragraphs 92 & 229 and concluded the following:

> Other ingredients in the core material of Lapidot further comprise about 0.1% to about 20% by weight of a surfactant in the dispersion (see 0092). Lapidot also discloses the amount of the precursor to be about 0.001% to about 99% by weight of the dispersion (see 0229). Hence, the weight ratio of the shell to the core material in Lapidot would overlap the presently claimed range of 5/95 to 25/75.

OOa, p. 5. Applicants disagree.

What is further misapprehended or overlooked is the fact that Lapidot's cited teachings relate to the "sol-gel precursors in the dispersion immediately prior to emulsification...." Lapidot, ¶ 229. Similarly, referring to Lapidot's paragraphs 80-*et seq.*, the passages describe a solids content of Lapidot's solid-in-oil dispersion. For example, Lapidot clearly teaches that the "solid active ingredient *in the dispersion* is between about 1% and about 95% by weight." Lapidot, ¶ 85 (emphasis added). With all due respect, neither of these two teachings of Lapidot would suggest the recited *weight ratio* of claim 1.

On one hand, refer to Lapidot's Example 3, which concerns encapsulating the antibiotic erythromycin using the water-insoluble room-temperature oil octylmethoxy cinnamate (OMC). In Lapidot's Example 3, 1.7g of erythromycin and 14.9 g of OMC were mixed with 19.5 g of TEOS. Lapidot, ¶ 247. The OMC & erythromycin account for 46%, and the TEOS accounts for 54%.[1] Similar results for ratios are inferable from Lapidot's other examples.

On the other hand, Example 1 of the present specification describes adding 276 g of OMC to 24 g of TEOS. The OMC accounts for 92%, and the TEOS accounts for 8.0%.[2] Similar results for ratios are inferable from the other examples in the present specification.

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[1] 1.7g + 14.9 g + 19.5 g = 36.1 g

(1.7g + 14.9 g)/36.1 g x 100% = 46%

19.5 g/36.1 g x 100% = 54%.

[2] 276 g + 24 g = 300 g

276 g / 300 g x 100% = 92%

24 g / 300 g x 100% = 8.0%

It would have been counter intuitive to expect to encapsulate a large percentage of OMC using a lesser relative amount of precursors. But, as noted of record, it was surprisingly found by the inventors that decreasing the weight ratio of the precursor to the core material to the range of 5/95 to 25/75 and performing the condensation-polymerization process in a pH of 2-7, enables an efficient encapsulation of the core material with high concentration of above 95% w/w (i.e., of between 96 to 99% w/w) of the core material and yet makes it possible to prevent leaching of the core material (including the active ingredient) from the microcapsules. This was confirmed by the examples in the present specification and was unexpected.

Also unexpectedly, it was found that although the weight ratio of the precursor to the core material was decreased from an exemplary embodiment having about 50/50 (*cf.*, for example, Lapidot) to the range of 5/95 to 25/75, the polymerization of the precursor was of high efficiency and a higher yield was obtained from the point of view of the quantity of silica developed on the shell of the microcapsule, as revealed by the high concentration of the core material and insignificant amount of the residual precursor in the reaction aqueous medium (in the form of colloidal silica) in which the microcapsules are produced. This was found to be highly advantageous since it minimized the environmental contamination, did not require treatment of the reaction waste water and thus simplified and lowered the cost of the process. These attributes were unexpected.

As such, the present rejection should be withdrawn.

concentration of the core material

As noted above, claim 1 recites a *concentration of the core material* in the following language:

> *wherein the concentration of the core material based on total weight of the microcapsules is 96% to 99% w/w.*

The present specification describes a procedure sufficient for determining the *concentration of the core material*. Spec. p. 39, ll. 22-30.

According to the Examiner, regarding the active ingredient material in the core, "Lapidot teaches about 1% to about 95% [0085]…. Thus, by teaching about 95%, Lapidot directly the presently claimed range." OOa, p. 5. Applicants disagree.

What is further misapprehended or overlooked is the fact that Lapidot teaches that the "solid active ingredient *in the dispersion* is between about 1% and about 95% by weight." Lapidot, ¶ 85 (emphasis added). Thus, here Lapidot is **not** referring to *concentration of the core material based on total weight of the microcapsules* per claim 1. As noted above when referring to Lapidot's paragraphs 80-*et seq.*, the passages describe a solids content of Lapidot's solid-in-oil dispersion. *Cf.* Lapidot ¶ 209 for solid-in-oil emulsions. A more relevant passage from Lapidot reads as follows: "Preferably, the load of active ingredient(s) in the microcapsules is between about 0.001% and 95% by weight of the microcapsules and more preferably, between about 5% and 80% by weight of the microcapsules." Lapidot, ¶ 126.

An objective of the present inventors was to obtain microcapsules having a high core load of between 96 to 99% w/w, which the Examiner should agree is a significant loading value.

Further the Examiner refers to paragraph [0092] as leading to the teachings of the precursor to core material ratio. The Examiner, with all due respect, misapprehends or overlooks claim language when noting the "weight ratio of the shell to the core." Claim 1 recites a *weight ratio of said* ***precursors*** *to said* ***core material***, and claim 1 further recites a *concentration of the core material based on* ***total weight of the microcapsules***. Thus, referring to the percentages regarding Lapidot's process ("weight ratio of the shell to the core") cannot teach or suggested a *concentration of the core material based on total weight of the microcapsules*, e.g., in a resultant product.

Furthermore, referring to the concentration of each ingredient of the dispersion prior to emulsification (as in paragraph [0229]) cannot teach the ratio between the precursor and the core material. It is further noted that in each example in Lapidot relating to the encapsulation of a solid (examples 4-6 relating to BPO), the active ingredient (i.e., the solid) was first either dissolved in another oil or dispersed in one, so that the ratio disclosed in the dispersion **prior to** emulsification is not the ratio between the **core material** and **the precursor** as recited in a *weight ratio of said* ***precursors*** *to said* ***core material*** per claim 1.

As indicated in the application, there is a widely recognized need and it will be highly advantageous to have microcapsules comprising a high concentration (above 95 percent w/w) of the core material (which includes the active ingredient) and yet which is capable of minimizing the contact between the active ingredient and the environment. Such high concentration of the core material is sufficient, for example, in order to obtain high Sun Protection Factor (SPF) values, or in many other applications where high loading of an encapsulated active ingredient in the composition is required.

Another advantage of the process of making an embodiment falling within the scope of the rejected claims is the elimination of the step of isolation of the microcapsules by centrifugation, filtration, re-suspension etc., which is used in the prior art in order to obtain a high concentration of particles in a final product. In the process disclosed in document Lapidot, isolation the microcapsules from the mother liquor was used in order to obtain a concentration of 40% w/w of sunscreen in the suspension, while, in the present application, no intermediate isolation step was needed due to the high loading of the active ingredient in the oil phase at the emulsion step and due to the high concentration of the oily phase in the emulsion - 50-90% w/w.

It is further noted that it was neither suggested nor expected by one of ordinary skill in the art, even those reading Lapidot, that higher loading is in any way possible with microcapsules obtained by in-situ polymerization of polymerized precursors, especially not in a much more acidic pH range of 2-7 and in a precursor to core material ratio of 5/95 to 25/75. This combination of conditions was neither taught nor suggested in Lapidot, which relates to more basic pH ranges and a ratio of precursor to core material of about 50/50, and therefore such high load of core material was not expected to be achieved.

For this reason the rejection should be withdrawn.

General

An analogous line of reasoning applies to claim 29 and the remaining rejected claims. For these reasons, the rejection should be withdrawn.

Rejoinder should be made.

Conclusion

Favorable reconsideration of the application is respectfully requested. It is believed that the present application is in condition for allowance.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 07-1337 and please credit any excess fees to such deposit account.

Respectfully submitted,

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